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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,333	03/08/2004	Jonathon H. Pinter	AH-RUBC:021US	4616

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EXAMINER

THOMAS, DAVID C

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/797,333	Applicant(s) PINTER ET AL.	
	Examiner David C. Thomas	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-152 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-152 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-111, 119-125, and 140-146, drawn to a method of preparing a DNA molecule, classified in class 435, subclasses 91.2 and 91.5.
 - II. Claims 112-115, drawn to a kit for performing a concomitant endonuclease/ligase reaction comprising an endonuclease, a ligase, an adaptor and a buffer, classified in class 435, subclass 183 and class 536, subclass 24.2.
 - III. Claims 116-118, drawn to a method of diagnosing a condition in an individual, classified in class 435, subclass 6.
 - IV. Claims 126-139, drawn to a method of immobilizing an amplified genome, classified in class 435, subclass 287.2.
 - V. Claims 147-152, drawn to a method of sequencing genomic DNA, classified in class 435, subclasses 6 and 91.1.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit comprising an endonuclease, a ligase, an adaptor and a buffer of Group I can be used to prepare

templates for cloning or primer extension assays, with or without addition of an adaptor as opposed to its use for performing a concomitant endonuclease/ligase reaction.

Searching the inventions of Groups I and II together would impose serious search burden. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for kits comprising an endonuclease, a ligase, an adaptor and a buffer of Group II and of methods of preparing a DNA molecule of Group I are not coextensive.

4. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation and different functions. The methods of preparing a DNA molecule of Group I can be used for preparation of DNA molecules for purposes of general amplification or primer extension, or preparing a DNA library, while the methods of Group III are used to identify specific sequences or sequence alterations representative of a condition found in specific genomic locations, such as a chromosome, by comparison to sequences from existing databases known to contain the representative sequences. For these reasons, the inventions of Groups I and III are unrelated.

Furthermore, searching the inventions of Groups I and III together would impose a serious search burden. The inventions of Groups I and III have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the

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search for methods of preparing a DNA molecule of Group I and methods of diagnosing a condition in an individual are not coextensive.

5. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation and different functions. The methods of preparing a DNA molecule of Group I can be used for preparation of DNA molecules for purposes of general amplification or primer extension, or preparing a DNA library, while the methods of immobilizing an amplified genome to a support of Group IV are used to prepare arrays, to remove contaminants from the immobilized genome or for further enzymatic treatments such as primer extension assays. The methods of preparing a DNA molecule involve fragmentation of a DNA molecule, modification of the termini, attachment of adaptors, and amplification, while the methods of immobilizing an amplified genome to a support involve covalent or non-covalent attachment of a plurality of DNA molecules to a solid surface. For these reasons, the inventions of Groups I and IV are unrelated.

Furthermore, searching the inventions of groups I and IV together would impose a serious search burden. The inventions of Groups I and IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search methods of preparing a DNA molecule of Group I and methods of immobilizing an amplified genome to a support are not coextensive.

6. Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation and different functions. The methods of preparing a DNA molecule of Group I can be used for preparation of DNA molecules for purposes of general amplification or primer extension, or preparing a DNA library, while the methods of Group V are used to identify specific sequences from a specific limited source such as an extinct species or a microorganism resistant to culturing, by sequencing cloned adaptor linked fragments. The methods of sequencing also involve cloning adaptor-linked fragments into a vector that are not performed in the methods of preparing a DNA molecule. For these reasons, the inventions of Groups I and V are unrelated.

Furthermore, searching the inventions of Groups I and V together would impose a serious search burden. The inventions of Groups I and V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for methods of preparing a DNA molecule of Group I and methods of sequencing genomic DNA are not coextensive.

7. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation and different functions. The kits for performing a concomitant

endonuclease/ligase reaction comprising an endonuclease, a ligase, an adaptor and a buffer of Group II can be used for preparation of DNA molecules containing adaptors attached to specific sequences generated by restriction endonuclease cleavage or for other uses such as cloning or primer extension assays, with or without addition of an adaptor, while the methods of Group III are used to identify specific sequences or sequence alterations representative of a condition found in specific genomic locations, such as a chromosome, by comparison to sequences from existing databases known to contain the representative sequences. The methods of diagnosing a condition in an individual do not use DNA fragments prepared by the kit of Group II. For these reasons, the inventions of Groups II and III are unrelated.

Furthermore, searching the inventions of Groups II and III together would impose a serious search burden. The inventions of Groups II and III have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for kits comprising an endonuclease, a ligase, an adaptor and a buffer of Group II and methods of diagnosing a condition in an individual are not coextensive.

8. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation and different functions. The kits for performing a concomitant endonuclease/ligase reaction comprising an endonuclease, a ligase, an adaptor and a buffer of Group II can be used for preparation of DNA molecules containing adaptors

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attached to specific sequences generated by restriction endonuclease cleavage or for other uses such as cloning or primer extension assays, with or without addition of an adaptor, while the methods of immobilizing an amplified genome to a support of Group IV are used to prepare arrays, to remove contaminants from the immobilized genome or for further enzymatic treatments such as primer extension assays. The methods of immobilizing an amplified genome to a support do not use DNA fragments prepared by the kit of Group II. For these reasons, the inventions of Groups II and IV are unrelated.

Furthermore, searching the inventions of Groups II and IV together would impose a serious search burden. The inventions of Groups II and IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for kits comprising an endonuclease, a ligase, an adaptor and a buffer of Group II and methods of immobilizing an amplified genome to a support are not coextensive.

9. Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation and different functions. The kits for performing a concomitant endonuclease/ligase reaction comprising an endonuclease, a ligase, an adaptor and a buffer of Group II can be used for preparation of DNA molecules containing adaptors attached to specific sequences generated by restriction endonuclease cleavage or for other uses such as cloning or primer extension assays, with or without addition of an adaptor, while the methods of Group V are used to identify specific sequences from a

specific limited source such as an extinct species or a microorganism resistant to culturing, by sequencing cloned adaptor linked fragments. The methods of sequencing also involve cloning adaptor-linked fragments into a vector that are not prepared using the kit of Group II. For these reasons, the inventions of Groups II and V are unrelated.

Furthermore, searching the inventions of Groups II and V together would impose a serious search burden. The inventions of Groups II and V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for kits comprising an endonuclease, a ligase, an adaptor and a buffer of Group II and methods of sequencing genomic DNA are not coextensive.

10. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation and different functions. The methods of Group III are used to identify specific sequences or sequence alterations representative of a condition found in specific genomic locations, such as a chromosome, by comparison to sequences from existing databases known to contain the representative sequences while the methods of Group IV involve immobilizing an amplified genome to a support for the purposes of preparing arrays, removing contaminants from the immobilized genome or for further enzymatic treatments such as primer extension assays. The methods of diagnosing a condition in an individual involve fragmentation of a DNA molecule, modification of the termini, attachment of adaptors, and amplification, while the methods

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of immobilizing an amplified genome to a support involve covalent or non-covalent attachment of a plurality of DNA molecules to a solid surface. For these reasons, the inventions of Groups III and IV are unrelated.

Furthermore, searching the inventions of Groups III and IV together would impose a serious search burden. The inventions of Groups III and IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for methods of diagnosing a condition in an individual of Group III and methods of immobilizing an amplified genome to a support of Group IV are not coextensive.

11. Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation and different functions. The methods of Group III are used to identify specific sequences or sequence alterations representative of a condition found in specific genomic locations, such as a chromosome, by comparison to sequences from existing databases known to contain the representative sequences while the methods of Group V are used to identify specific sequences from a specific limited source such as an extinct species or a microorganism resistant to culturing, by sequencing cloned adaptor linked fragments. The methods of sequencing also involve cloning adaptor-linked fragments into a vector that are not performed using the methods of Group III. For these reasons, the inventions of Groups III and V are unrelated.

Furthermore, searching the inventions of Groups III and V together would impose a serious search burden. The inventions of Groups III and V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for methods of diagnosing a condition in an individual of Group III and methods of sequencing genomic DNA of Group V are not coextensive.

12. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation and different functions. The methods of Group IV involve immobilizing an amplified genome to a support for the purposes of preparing arrays, removing contaminants from the immobilized genome or for further enzymatic treatments such as primer extension assays while the methods of Group V are used to identify specific sequences from a specific limited source such as an extinct species or a microorganism resistant to culturing, by sequencing cloned adaptor linked fragments. The methods of sequencing genomic DNA involve fragmentation of a DNA molecule, modification of the termini, attachment of adaptors, and amplification, while the methods of immobilizing an amplified genome to a support involve covalent or non-covalent attachment of a plurality of DNA molecules to a solid surface. The methods of sequencing also involve cloning adaptor-linked fragments into a vector that are not performed using the methods of Group IV. For these reasons, the inventions of Groups IV and V are unrelated.

Furthermore, searching the inventions of Groups IV and V together would impose a serious search burden. The inventions of Groups IV and V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for methods of immobilizing an amplified genome to a support of Group IV and methods of sequencing genomic DNA of Group V are not coextensive.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

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found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David C. Thomas 9/15/06

David C. Thomas
Patent Examiner
Art Unit 1637

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JEFFREY FREDMAN
PRIMARY EXAMINER

9/15/06